NOV 2 2012

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: October 28, 2012

Submitter: GE Healthcare, (GE Medical Systems SCS)
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Device: Trade Name: **FlightPlan for Liver**
Common/Usual Name: Picture Archiving and Communications System
Classification Names: 21CFR 892.2050, Class II
Product Code: LLZ

Predicate Device(s): K041521, **Volume Viewer** Plus

Device Description: **FlightPlan for Liver** is a post-processing software application for use with interventional fluoroscopy procedures, using 3D rotational angiography images as input. It operates on the AW VolumeShare 4 [K052995] and AW VolumeShare 5 [K110834] platform. It is an extension to the Volume Viewer application [K041521] utilizing the rich set of the 3D processing features of Volume Viewer.

FlightPlan for Liver delivers post-processing features that will aid physicians in their analysis of 3D X-ray images of the liver

arterial tree.

Intended Use: **FlightPlan for Liver** is a post processing software package that helps the analysis of 3D X-ray images of the liver arterial tree. Its output is intended as an adjunct means to help identify arteries leading to the vicinity of a hypervascular region of interest in the liver.

Indications for Use **FlightPlan for Liver** is a post processing software package that helps the analysis of 3D X-ray images of the liver arterial tree. Its output is intended as an adjunct means to help identify arteries leading to the vicinity of hypervascular lesions in the liver. This adjunct information may be used by physicians to aid them in their evaluation of hepatic arterial anatomy during embolization procedures.

Technology: FlightPlan for Liver employs the same fundamental scientific technology as its predicate device (Volume Viewer).
When FlightPlan for Liver is active, all Volume Viewer functionalities are available at the same time.
Additionally FlightPlan for Liver includes an algorithm to highlight the potential vessel(s) in the vicinity of a target.

Determination of Substantial Equivalence: FlightPlan for Liver when used together with Volume Viewer delivers functionality of comparable type that is substantially equivalent to the predicate device listed above and complies with the same or equivalent standards and has the same Intended Use.

Summary of Non-Clinical Tests:
FlightPlan for Liver complies with voluntary standards IEC 60601-1-4, IEC 62304 and IEC 62366.
The following quality assurance measures were applied to the development of the software application:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance and Safety testing (Verification). The Verification Tests of the FlightPlan for Liver were performed in accordance with device Design Verification Plan and with device Verification Procedure. The verification tests were performed to check whether the application works as required and whether the risk mitigations have been correctly implemented. Performance testing consists of computing time

of algorithm on several data. The Verification confirms that the Design Output meets the Design Input (Product Specifications) requirements.

- Final acceptance testing (Validation). The Validation Tests of the FlightPlan for Liver were executed in accordance with device Design Validation Plan and with device Validation Procedure. The Validation tests consist of typical use case scenario described by the sequence of operator actions. The Design Validation confirms that the product fulfills the user needs and the intended use under simulated use conditions.

Summary of Clinical Tests:
This premarket submission included a clinical test to demonstrate the safety and effectiveness of FlightPlan for Liver.

In this retrospective study (44 subjects representing a total of 66 tumors) performed on a database of hypervascular liver tumors in patients subsequently treated by chemoembolization, the output of FlightPlan for Liver was compared to a reference reading established by two senior interventional oncologists.

The clinical data provided to support that FlightPlan for Liver provides adjunct information that may be used by physicians to aid them in their evaluation of hepatic arterial anatomy during embolization procedures was not designed nor intended to support a claim of an improvement in clinical outcomes of such procedures, and no such claim is being made.

Conclusion: GE Healthcare considers the FlightPlan for Liver application to be as safe and as effective as its predicate device, and its performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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GE Healthcare, GE Medical Systems SCS
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Re: K121200
Trade/Device Name: FlightPlan for Liver
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 8, 2012
Received: October 15, 2012

Dear Ms. Alloian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

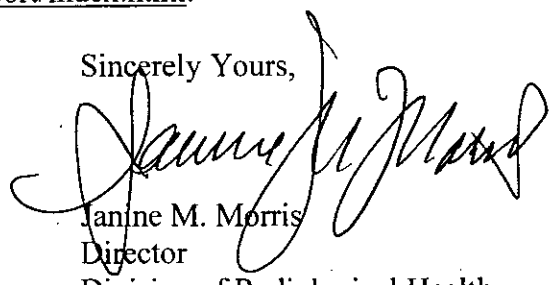
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

K121200

Indications for Use

510(k) Number (if known): **K121200**

Device Name: **FlightPlan for Liver**

Indications For Use:

FlightPlan for Liver is a post processing software package that helps the analysis of 3D X-ray images of the liver arterial tree. Its output is intended as an adjunct means to help identify arteries leading to the vicinity of hypervascular lesions in the liver. This adjunct information may be used by physicians to aid them in their evaluation of hepatic arterial anatomy during embolization procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K121200